EXHIBIT P

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July 12, 2019

VIA DAB E-FILE

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building, Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Re: ALJ Appeal No.: 1-8390277469
Decision Date: June 19, 2018
Appellant: A. Prosser
Beneficiary: A. Prosser
HICN: 4R87U71QM75
Dates of Service: 1/16/18-4/16/18
Service: E0766
Our Ref. 19-51

Dear Medicare Appeals Council:

Ms. Anniken Prosser hereby appeals the attached June 19, 2019 unfavorable decision by Administrative Law Judge Joseph Grow with respect to the above-identified case. See Attachment 2. Appellant appeals the unfavorable portion of the decision based on mistake of fact and mistake of law.

I. The issues to be considered in the appeal are:

1. Did the ALJ conduct a *de novo* hearing and render a decision based on the record?

2. Did the ALJ Appellant reasonably believe that LCD L34823 did not apply to her newly diagnosed glioblastoma?

3. Was Appellant entitled to coverage based on collateral estoppel?

4. Did Appellant submit sufficient documentation to satisfy Medicare coverage criteria?

5. Was Appellant entitled to payment based on the waiver of limitation of liability?

II. Introduction

Ms. Prosser was prescribed an Optune system for her newly diagnosed glioblastoma (GBM). The Optune system delivers tumor treatment field therapy (TTFT). TTFT creates an electrical field that disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2013, the FDA approved, through its more rigorous review process, the Optune device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. The initial FDA approval was for recurrent glioblastoma. The FDA then approved the Optune device for newly diagnosed glioblastomas. During the clinical trial for newly diagnosed glioblastomas, the interim TTFT results were so compelling (i.e., the treatment was able to show significant clinical benefit) that the Data Safety Monitoring Board recommended early termination of the study to enable patients not receiving the treatment to cross over and receive the treatment deeming it to be unethical to withhold TTFT from those not receiving it. The FDA agreed.

All the claims at issue were denied by the contractor citing LCD L34823 which simply states TTFT will be denied as not reasonable and necessary. The QIC denied the claims citing the LCD and finding that the "currently published studies in the medical literature do not clearly document the effectiveness of this device." Significantly, the DMAC medical directors issued a letter indicating that LCD L34823 does NOT apply to newly diagnosed glioblastoma and that they intend to undertake the LCD development process for the same. Despite this clear statement from the DMAC medical directors, the ALJ found the LCD applied.

The ALJ stated that Appellants arguments were challenges to the underlying record on which the LCD was based and asserted he did not have the LCD record before him.

III. Satisfaction of Medicare Coverage Criteria

All of the claims initially were denied by the Medicare contractor on the basis that TTFT was not reasonable and medically necessary generally and that the peer-reviewed literature does not document the effectiveness of the device. With respect to the second point, the evidence to the contrary is overwhelming. The data from the clinical trial for newly diagnosed glioblastomas demonstrated such remarkable effectiveness that the study was terminated early to enable those not receiving treatment during the clinical trial to receive the treatment. The FDA approved the device as effective. Because the peer-reviewed literature is so compelling, the NCCN guidelines give TTFT a level 1 recommendation for newly diagnosed glioblastomas, i.e., uniform agreement exists among the experts based on the highest level of evidence, that TTFT should be offered to those newly diagnosed with a glioblastoma. Thus, the experts agree that the peer-reviewed literature meets the highest level of evidence possible. The ALJ failed to consider the peer-reviewed literature – a primary Medicare coverage criterion.

Further, the ALJ's analysis fails to reflect consideration of the other Medicare coverage criteria, i.e., the consensus of experts (reflected in the NCCN guidelines and adoption by all the major medical centers in the United States), and acceptance by the relevant medical community (again in view of the inclusion in practice guidelines, the device has been prescribed in every state by hundreds of clinicians and is covered by all major payers). Thus, to the extent the ALJ found that the LCD was silent with respect to coverage for newly diagnosed GBM, the ALJ should have undertaken the foregoing analysis, which she did not. Further, even if the ALJ found the LCD did cover newly diagnosed GBM, notwithstanding the clear statement of the DMAC medical directors, the ALJ could have chosen not to give it deference in view of the overwhelming evidence that TTFT meets Medicare's coverage criteria.

It is difficult to follow the ALJ's statement that the CRD ruling "does include change in the treatment protocol it does not, on its own, invalidate the LCD." The Judge in the Civil Remedies Division found the LCD record did not support the validity of the LCD and invited the parties to supplement the record. The DMAC only submitted the Program Integrity Manual and indicated that it did not have witnesses to defend the LCD. Because the existing evidence did not support the LCD, and the DMACs offered no additional evidence, it is clear that the LCD will be revised or invalidated soon based on the overwhelming evidence that TTFT meets Medicare coverage criteria. It is unclear what "treatment protocol" the ALJ is referencing.

IV. Errors of Law and Fact - Procedural Defect

The claims were denied below on the basis that the TTFT generally is not covered. The ALJ's decision appears to confuse the distinction between an LCD challenge and its implication for a claims appeal. A beneficiary can file an appeal of a denied claim without challenging a coverage policy. ALJs can make payment for a claim and choose not to apply an LCD in an individual case. The fact that an LCD challenge or reconsideration was filed is additional evidence that the LCD does not conform to the MPIM requirements and provides another basis for declining to follow an LCD. However, the existence of an LCD challenge or reconsideration in no way undercuts the ability of a Medicare beneficiary to argue that the LCD should not be given deference in his or her case based on the obvious deficiencies of an LCD. The ALJ appeared to think that the beneficiary was challenging the LCD in the claim appeal process when she was simply indicating that it should not be applied in her case (as opposed to all Medicare beneficiaries) based on her medical condition and need for the treatment.

In either event, the ALJ stated he did not have the LCD record before him. However, Ms. Prosser had submitted the LCD Record Exhibit List from the LCD challenge process which showed that the Medical Directors had not considered any of the evidence regarding TTFT that had evolved since 2014. Further, after the hearing, but before Judge Grow issued his decision, the Civil Remedies Division found that the LCD record did not support the validity of the LCD under the reasonableness standard. Thus, the LCD should not have been applied against a Medicare beneficiary battling a life-threatening illness. As numerous judges have found, an LCD that has not kept pace with clinical and scientific developments, and which precludes coverage of a treatment that is the standard of care, should not be applied against Medicare beneficiaries.

The ALJ failed to consider the implications of the CRD ruling when denying coverage of a treatment that is the standard of care.

Finally, Ms. Prosser received a prior favorable ALJ decision on other dates of service for the same device for the same condition. See ALJ No. 1-8416188648. Accordingly, the Secretary is estopped from denying her claims for TTFT. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues. As noted by a unanimous Supreme Court:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

See Astoria Federal Savings and Loan Assoc. v. Solimino, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). No basis exists for the Secretary to ignore the prior coverage rulings for this Medicare beneficiary.

IV. Limitation of Liability

The DMAC medical directors indicated the relevant LCD does not apply to newly diagnosed glioblastoma. Further, the Medicare beneficiary could not have reasonably known that the standard of care for newly diagnosed glioblastoma would not be covered by Medicare. In view of the overwhelming peer-reviewed literature, the consensus of medical experts and the widespread, nationwide adoption by payers and clinicians, Ms. Prosser could not have reasonably known the Optune system would not be covered by Medicare. Further, nothing distinguishes her case from the numerous claims paid by Medicare for medically similar Medicare beneficiaries. Indeed, Ms. Prosser received a favorable ALJ decision regarding Medicare coverage for TTFT for her GBM. Accordingly, she is entitled to coverage under Medicare's limitation of liability provisions.

V. Conclusion

The Optune system was reasonable and medically necessary when it was provided to the Ms. Prosser. The ALJ committed fundamental errors of law when he denied a Medicare beneficiary coverage of a service which has extended her life. Judge Grow applied an LCD which on its face showed that it failed to consider any of the clinical and scientific developments that had occurred over the past five years and which the Civil Remedies Division found invalid under the reasonableness standard. Based on the foregoing, Judge Grows's decision should be reversed and the MAC should be ordered to cover the Optune system for Ms. Prosser.

Please contact me if you have any questions regarding this appeal.

Yours very truly,

Debra Pistorino Parrish

Enclosures:
Appointment of Representative
June 19, 2019 ALJ Decision

cc: A. Prosser
C2C Innovative Solutions, Inc.

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January 2, 2020

VIA E-file
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, DC 20201

RE: Request for Escalation
Appellant/Medicare Beneficiary: Anniken Prosser
HICN: 4R87U71QM75
ALJ Decision Date: June 19, 2019
ALJ Appeal Nos.: 1-8390277469
Council No.: M-19-2233 (filed July 12, 2019)
Our Ref: 19-51

Dear Medicare Appeals Council:

Ms. Anniken Prosser has received two favorable ALJ decisions finding TTFT meets Medicare coverage criteria for her. See ALJ Nos. 1-8380637906 and 1-8416188648. The Secretary chose not to appeal the decisions and they have become final. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues with respect to Ms. Prosser. As noted by a unanimous Supreme Court, "We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality." *See Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). The application of issue preclusion would not work as basic unfairness against the Secretary and there are no special circumstances that would make it unfair to apply the doctrine.

The above-captioned Medicare beneficiary appeal has been pending for more than 90 days. Accordingly, pursuant to 42 C.F.R. §405.1132, Ms. Prosser requests escalation of the above-captioned claims to District Court.

Sincerely,

Debra M. Parrish

Debra M. Parrish for
Medicare Beneficiary Anniken Prosser